REMARKS

This Amendment and Remarks are filed in response to the Final Office Action dated November 21, 2007, wherein all claims stand rejected.

Status of the Claims

Claims 1-57 are canceled. New claims 59-86 are added.

Terminal Disclaimer

Examiner acknowledges receipt and makes of record the terminal disclaimers in response to the obviousness double patenting rejections based on US Patent 6,982,091 ('091 patent), US Patent 6,086,909 ('909 patent), and copending applications 10/335, 759,11/126,863; 11/208,209; 11/180,076; and 11/522,126.

Declaration under 37 CFR 1.130

Receipt of the signed declaration of Richard J. D'Augustine dated August 10, 2007, declaring common ownership of the instant claimed subject matter and US Patent 6,905,701, US Patent 6,086,909 at the time the later invention was made, has been considered and made of record.

It was not executed in accordance with either 37 CFR 1.66 or 1.68. It does not include the notary's seal and venue. Besides, a declaration filed under 37 CFR 1.130 is insufficient to overcome the 102(b) rejection with respect to US patent 6,086,909 (see Office action mailed 5/10/07, pages 7-9).

Applicants enclose herewith a newly executed declaration by Mr. Richard D'Augustine that meets requirements of 37 CFR 1.68.

Non-statutory Obviousness-Type Double-Patenting

Examiner repeats his non-statutory double patenting rejections and adds another patent, namely patent 6,905,701 as making the instant claims unpatentable.

Examiner advises that a timely filed terminal disclaimer in compliance with 37 CFR 1.321 © or 1.321 (d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement and, effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Specifically, claims 47-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-27 of US Patent 6,905,701 ('701). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

In particular, claim 24 of '701 is directed towards a medicated intravaginal device for a transmucosal delivery of bisphosphonates to the general circulation. In view of the fact that the treatment populations overlap, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant invention with a reasonable expectation of success.

Examiner concludes that claims 29-46 are deemed obvious variants of the limitations of the patented subject matter claimed in '701. For the same reasons stated above, claims 29-46 are similarly deemed to be obvious variants of the limitations of the patented subject matter of claims 21-33 of U.S. Patent 6,982,091 ('091).

Applicants disagree. Rejected claims are no longer pending in the

application, however, to remove this rejection, Applicants respectfully point out that Examiner is rejecting claims 47-58 over patent 6,905,701 as well as claims 29-46 over the same patent and adds to this mixture also rejection of claims 29-46 over patent 6,982,091.

First, claims 29-46 were, at the time of this rejection, no longer pending in the application. Second, the Terminal Disclaimer for patent 6,982,091 was filed on August 10, 2007. Third, Applicants disagree that the claims of the '701 patent and the instant claims contain "the treatment population overlap", as Examiner termed it.

The 701 patent, and particularly claim 24, is directed to a medicated intravaginal device, such as vaginal tampon, capsule, applicator, tablet, bioadhesive tablet, pessary, cup or sponge, for transmucosal delivery of bisphosphonates into systemic circulation wherein said device is **incorporated** with a transmucosal composition comprising bisphosphonate, about **1.5%** of hydroxypropyl methylcellulose, saturated triglyceride of fatty acid and ethoxydiglycol. Claim 25 of '701 patent clearly defines a composition to be formulated as a film or foam, among others, and then being **incorporated** into the vaginal device. For the transmucosal delivery in '701 the film or foam compositions has to contain hydroxypropyl methylcellulose, saturated triglycerides and ethoxydiglycol.

Claims in the instant application are directed to a foam or film device for topical delivery through vaginal, nasal, buccal scrotal or labial epithelium. The film or foam device is preformed into a solid or semi-solid foam tampon, foam tablet, foam cylinder, foam or film strip, foam or film pad, foam or film pillow, foam or film tube, foam or film sheet, foam or film sphere, foam or film ring, foam bead or a single or double sided foam or film sheet, or is a liquid preparation

that forms a foam or film layer device upon contact with an epithelial tissue or with a surface of non-foam or non-film device made of different material. The film or foam of the instant claims is thus not incorporated into the vaginal device but is the vaginal device.

By virtue of the substrate polymer required in claim 47, mucoadhesive agents, penetration enhancers and carriers are not needed for formation of the foam or film device.

It is respectfully submitted that the claims of '701 and the instant application do not claim the same subject matter and do not even concern the overlapping matter to warrant the filing of Terminal Disclaimer.

The nonstatutory double patenting rejection should be withdrawn. It is so respectfully requested.

In addition, Examiner provisionally rejects claims 29-46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following: claims 49-54, 55, 57-79 of copending Application No. 10/335,759; claims 1-15 of copending Application No. 11/126,863, claims 45-53 of copending Application No. 11/208,209, claims 1-55 of copending Application No. 11/180,076, and claims 20-23 of copending Application No. 11/522,126, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other for essentially the same reasons stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

These rejections are being maintained because the corresponding terminal disclaimers have not been approved.

Examiner did not indicate if the approval of previously filed Terminal Disclaimers is an internal matter of the PTO or if there was something wrong with the Disclaimers. Clarification is requested.

Also, as pointed out above, claims 29-46 are no longer pending in the application and the rejection would thus seem to be moot.

Rejections under 35 USC 112, Second Paragraph

Claim 48, 49, 53, 54 and rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the terms "suppocire AS2X," suppocire CM, Witepsol H15, Witepsol W25, carbopol, poloxamer," but fails to state the full generic name of these apparent brand names. It is suggested that this specific rejection may be overcome by either replacing the terms with their full generic names or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the terms in the claim set. It is also noted that even though the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants disagree. Claim 53 is canceled. However, to overcome the rejections in the new claims, applicants provide generic description of the rejected terms.

Claim 48 recites the term "anti-HIV agent" but fails to state the full meaning of the term at the first occurrence the term is recited in the claim set. This limitation is vague and indefinite because it is not clear what "anti-HIV agent" means. It is suggested that this

specific rejection may be overcome by either replacing the term "anti-HIV agent" with the full name or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the term "anti-HIV agent" in the claim.

Applicants disagree. Claim 48 is canceled.

Claim 49 recites the terms "COX-2 or COX-1;" "AZT;' gastrine G17," but fails to state the full meaning of the term at the first occurrence the term is recited in the claim set. This limitation is vague and indefinite because it is not clear what these terms mean. It is suggested that this specific rejection may be overcome by either replacing the terms "COX-2 or COX-1;" "AZT;' gastrine G17," with the full name or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the terms in the claim.

Applicants disagree. Claim 49 is canceled. However, where appropriate in the new claims, Applicants amended claims to replace "COX" inhibitors with cyclooxygenase inhibitors, "AZT" with azidothymidine and "gastrin" with gastrointestinal hormone gastrin.

Claim 54 recites the term "from about to about 5% to about 70%, by weight." This claim is indefinite because it is unclear what the term means. Claim 54 is canceled.

In view of cancellation of claims 48, 49, 53 and 54, the rejection under 35 USC 112, second paragraph, is moot.

Claim Rejections under 35 USC 102

Claims 47-58 are rejected under 35 use 102(b) as being anticipated by Harrison et al. (US Patent 6,086,909).

The above discussion in connection with the Response to applicant's arguments/remarks regarding the rejection under 102(b) is incorporated by reference.

Claims 47-58 are canceled, however, since some of the rejections, unless overcome, could be advanced against the newly submitted claims, Applicant provides the following arguments.

Examiner maintains that Harrison et al.(6,086,909) teach devices, compositions and methods for treating dysmenorrhea by intravaginal administration of therapeutic and/or palliative drugs to the uterus (column 1, lines 13-16).

Applicants agree that Harrison teach devices, compositions and methods for treating dysmenorrhea by intravaginal administration of therapeutic and/or palliative drugs to the uterus. Such devices are vaginal tampons, vaginal tampon-like device, vaginal ring, vaginal pessary or vaginal sponge generally used for insertion to vagina for contraceptive or therapeutic purposes.

Applicants disagree that such teaching and such devices anticipate the previous and newly added claims.

Instant claims are directed either to foam or film devices for topical delivery of therapeutically effective agents to a vaginal, nasal, buccal, scrotal or labial epithelium and through such epithelium into a systemic circulation. Differences between the two inventions are: the Harrison devices are typical vaginal devices not useful for delivery to buccal, labial or nasal mucosa; the Harrison devices are not made solely of foam or film; the Harrison's devices deliver the composition through the vaginal wall to uterus whereas the instant devices deliver the drug to the nasal, buccal, labial or vaginal mucosa and/or through such mucosa into systemic circulation; and the instant devices are degradable or non-degradable foam or film stand alone devices made of a substrate polymers having controllable fast, slow or pulsating release rate of the drug from such devices.

Harrison does not disclose the film devices at all and insofar as the foam devices, Harrison's devices only incorporate foam as part of the tampon, as seen in Figure 15, but are not itself made of foam or film.

Examiner argues that Harrison et al., teach controlled release drug delivery system in the form of, for example, a tampon-like device, vaginal ring, pessary, tablet, paste, suppository, vaginal sponge, bioadhesive tablet, bioadhesive microparticles, cream, lotion, foam, ointment, or gel (column 9, lines 5-67).

Applicants disagree that such teaching and such systems anticipate the instant claims. What Examiner is citing is the controlled release system, not the device. Specifically, Harrison, Col. 9, lines 5-10 state: "The controlled release drug **delivery system** can be in the form of..... foam, paste, ointment or gel. Each of these systems is discussed below". The controlled release system is different from the device. Nowhere Harrison discloses a foam tampon, as such, as a device or a film, as such, as a device. The foam is disclosed only as a section, portion, cup or scoop connected with the tampon, which is further connected to a bladder filled with medication (Col 12, lines 23-37). There is no disclosure of substrate materials being in combination with the drug and formulated into a film or foam.

Examiner argues that Harrison et al., teach various tampon like devices which can be used to deliver drugs for the treatment of dysmenorrheal wherein the drug is incorporated into the device via numerous methods (column 9, lines 29-34).

Claim 47 recites the term "[a] foam or film device for topical delivery of a therapeutically effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium."

Examiner argues that Harrison et al. teach that the active drug can be incorporated into a gel-like bioadhesive reservoir in the tip of the device, or the drug can be in the form of a powdered material positioned at the tip of the tampon, or the drug can also be dissolved in a coating material which is applied to the tip of the tampon, or the drug can be incorporated into an insertable suppository which is placed in association with the tip of the tampon (column 9, lines 36-45).

Applicants disagree and fail to see a rationale for this comment and rejection. The film or foam device of the instant invention is prepared from the substrate polymer in combination with a drug. The section Examiner is citing discloses tampon-like devices into which the drug can be incorporated by way of a gel-like bioadhesive reservoir or as a powdered material in the tip of the device, or absorbed into tampon fibers or dissolved in a coating.

The previous or instant claims do not claim any such arrangement. Instant claims are directed to either the foam or the film device that is formed primarily from the substrate polymer in combination with the drug, surfactant, plasticizer and penetration enhancer.

Examiner cites various instant claims 47, 50, 55-58 as those when given their broadest reasonable possible interpretation clearly overlaps with the teaching of Harrison et al.

Examiner argues that Claim 47 recites the term "a foam or film pad," "a foam or film strip," " a solid or semi-solid foam tampon".

Applicants disagree. Harrison does not disclose foam or film pad, strip or solid or semi-solid tampon at all.

Examiner argues that Claim 50 recites the term "conventional tampon, ring, strip, pad, pillow, sheet, tube, sphere".

Applicants disagree. The claim 50 was dependent on claim 47

containing the limitation "or is a liquid preparation that forms a foam or film layer device upon contact with an epithelial tissue or with a **surface of non-foam or non-film device** made of different material" applying to the claim 50 directed to the device made of different material being "conventional tampon, ring, strip, pad, pillow, sheet, tube, sphere".

Harrison additionally does not disclose a liquid preparation that would form a foam or film on the tampon or another device.

Examiner argues that Claim 55 recites the term "said composition further comprises a therapeutically acceptable additive or excipient, wherein said additive or excipient is a solubilizing agent, buffering agent, filler, preservative, plasticizer, surfactant or anti-oxidant".

Applicants disagree. Claim 55 was limited by limitation in previous claims 51-54 that are further limited by claim 47. Harrison does not disclose a foam or film made of the substrate polymer at all, consequently it cannot anticipate foam or film that contain further excipients.

Examiner argues that Claim 56 recites the term "a single layer or multiple layers of a single or double-sided sheet".

Applicants disagree. Harrison does not disclose the term "film device" at all.

Examiner argues that Claim 57 recites the term "wherein said therapeutically effective agent is incorporated into or attached to one side or both sides of the film".

Applicants disagree. Since Harrison does not disclose the film device, the drug incorporated or attached to one side or two sides cannot be anticipated.

Examiner argues that Claim 58 recites the term "wherein said

therapeutically effective agent is incorporated into said foam before the foam formation or be coated on the inner pores of prefabricated foam".

Applicants disagree. Harrison does not disclose the foam device as such. He does not disclose that the drug is incorporated into the foam or coated on the inner pores of prefabricated foam.

Based on the detailed description of each claim Examiner is citing as anticipatory, Applicants disagree with the Examiner and submit that the claims have to be read in their entirety including all limitations of the prior claims in order to judge if they are anticipated. Applicants respectfully submit that they are not.

Examiner further argues that Harrison et al. teach a controlled release drug delivery system comprising non-limiting biocompatible excipient for applying the an active agent, including a lipophilic carrier or a hydrophilic carrier e.g. polyethylene glycol; muco-adhesive agents such as alginate and pectin; and penetration enhancers (col. 2, third full par.).

Applicants disagree. Applicants respectfully submit that Examiner is not reading the independent claim 47 correctly. Claim 47 and now a new claim 59 clearly claim the film or foam (claim 77) that is prepared solely from a listed substrate polymer and is used in combination with a drug. It can be used as such or some other compounds may be added to it. When they are added to it, they are still added to the film or foam device that is formed from the substrate polymer, as listed in new claims 59 and 77.

Nowhere in Harrison are such devices described, alluded to or implied.

Examiner argues that polyethylene glycol is a film-forming polymer

as evidenced by the teaching of Samour et al. (US Patent 5,807,957, see especially col. 18, Examples 4-6).

Applicants disagree. Samour discloses a cationic film-forming polymer compositions for topical delivery of drugs to the skin. Examiner's reference to Semour as disclosing that polyethylene glycol is a film-forming polymer clearly shows that Examiner does not interpret the claim 47 correctly. There, the foam or film is prepared solely from the substrate polymer. Samour adds polyethylene glycol (diol) to a mixture of hydrocarbyl terminated polyethylene oxide, such as polyethylene glycol methyl ester or butyl ester, and diisocyanate, such as methylene diisohexyl or hexamethylene.

Examiner further cites claims 47, 51 and 52 as reciting components which also overlap with the teaching of Harrison.

Claim 47 recited the terms "polyethylene glycol," "collagen," pectin," "alginic acid".

Applicants disagree. Harrison does not disclose the film anywhere other than the covering plastic film forming umbrella, thus it cannot anticipate claim 47 or the new claims.

Examiner argues that Claim 51 recites the term "polyethylene glycol".

Applicants disagree. Harrison does not disclose the film device at all.

Examiner argues that Claim 52 recites the term "said composition further comprises a penetration enhancer, ... mucoadhesive agent, hydrophilic or hydrophobic release modifier".

Applicants disagree. The film is not disclosed by Harrison. Therefore, the film containing a substrate polymer, penetration enhancer, surfactant and plasticizer.

Examiner argues that in Figure 6, the tampon device includes a distal porous foam section, which is preferably a soft, light weight, physiologically inert foam material of polyurethane, polyester, polyether, or other material such as collagen (column 10, lines 28-40).

Applicants disagree. The foam described in the Harrison application is a part of a tampon drug delivery system wherein the tampon device includes a distal porous foam section which is in the shape of a cup (Col. 10, lines 30-34). Given most opportune interpretation to Harrison invention, the foam is in the form of a cup having in the center a non-porous tube clearly providing a support for the foam cup. If such cup were to be inserted into vagina without supporting tampon, it would not be able to sustain its cup shape without such support. The instant foam as claimed in claims 77-86 is a stand alone device that has a form and shape designed for its intended purpose. Thus, for vaginal use, the foam has a form of a solid or semi-solid foam tampon, foam tablet, foam cylinder, foam strip, foam pad, foam pillow, foam tube, foam sheet, foam sphere, foam ring, foam bead or a single or double sided foam. Harrison described no such foam device.

Examiner submits that in one aspect, the invention provides a method for treating a human female suffering from dysmenorrheal comprising contacting the vaginal epithelium of the female with a pharmaceutical agent selected from the group consisting of nonsteroidal anti-inflammatory drugs, anti-prostaglandins, prostaglandin inhibitors, COX-2 inhibitors, local anesthetics, calcium channel blockers, potassium channel blockers (column 1, line 66 to column 2, line 16). Claim 48 recites the term "non-steroidal anti-inflammatory agent," "anti-osteoporosis agent," "anti-HIV agent;" and claim 49 recites the

term "COX-2 or COX-1 inhibitor agent".

Applicants disagree. The instant invention is directed to a stand alone film or foam device prepared from a substrate polymer. Such device delivers a therapeutically active agent. There are many devices known in the art that would deliver drugs named by Examiner. The drug entity has no meaning in anticipation. Just because it is the same drug or class of drugs it does not anticipate the instant claims when such drugs are delivered using devices that are not disclosed by anticipatory reference (Harrison) and or are formulated in a different way.

Examiner argues that Harrison et al. teach that non-limiting examples of nonsteroidal anti-inflammatory drugs suitable for practice of the invention includes ketorolac (column 2, lines 17-21; see also Example 4 at columns 16-18).

Applicants disagree. Harrison may be teaching what Examiner says but Harrison is not teaching a combination of these drugs with a film or foam stand alone device.

Examiner further argues that Harrison et al. disclose methods for combining the pharmaceutical agent with a drug delivery system for intravaginal delivery of the agent; drug delivery system include a tampon device, vaginal ring, pessary, tablet, vaginal suppository, vaginal sponge, bioadhesive tablet, bioadhesive micro particle, cream, lotion, foam, ointment, solution and gel (column 2, second full paragraph).

Applicants disagree. Examiner is misinterpreting Harrison teachings as outlined in Col 2, second full paragraph. That paragraph reads "combining the pharmaceutical agent with a drug delivery system". The delivery system of Harrison includes devices, methods and

compositions for localized transvaginal delivery of drugs to the uterus for treatment of dysmenorrhea (Col. 1, lines 53-56). The devices are tampon, ring, pessary, tablet and vaginal sponge. The compositions are vaginal suppository, bioadhesive tablet, bioadhesive micro particle, cream, lotion, foam, ointment, solution and gel. These compositions are administered directly to the vagina as such or they can be somehow attached to the vaginal device. Quite clearly, the foam as listed in Harrison means the foam like a shaving foam that can be introduced into vagina as a composition and not as a solid device. There is no teaching in the Harrison reference other than when the foam is attached to the tampon as a cup supported by the solid tube of a stand alone foam device. There is no disclosure of the method for preparation of the foam device as a stand alone device that would be even similar to the instant foam device.

Examiner further tries to find in Harrison some reference to a film. He cites column 3, lines 55-67 as teaching the film device:" In one embodiment, a tampon device is sheathed in a thin, supple, non-porous material such as a plastic film or a coated gauze that surrounds the absorbent tampon material like a skirt and opens like an umbrella when it comes in contact with the vaginal environment".

Applicants disagree. The film referred to in Harrison is a plastic film used as a sheathing material surrounding the vaginal tampon. A function of such sheathing plastic film is to surround the absorbent tampon material like a skirt and to open like an umbrella when it comes in contact with vaginal wall. If Examiner would continue to read the Harrison reference, he would find out that thus sheathed tampon is encircled with a band of drug suspended in a wax-like carrier that melts at the body temperature. When the sheathed tampon encircled with

the drug band is inserted into vagina, the wax melts and the drug is released from the wax band. To prevent a loss of the melted drug, the plastic film or gauze umbrella opens and prevents a leakage of the drug from vagina (Col. 3, lines 60-67). The film or gauze has no function in drug delivery. The Harrison's film is typically made of a plastic film similar to cling wraps or bags used for food storage (Col. 12, lines 52-29) and may be made of other materials such as gauze, cloth, tulle, cotton or netting material. These materials have no resemblance to the instant film made of the substrate polymer.

Examiner argues that Harrison et al. teach a controlled release drug delivery system comprising non-limiting biocompatible excipient for applying the agent including a lipophilic carrier or a hydrophilic carrier e.g. polyethylene glycol; muco-adhesive agents such as alginate and pectin; and penetration enhancers e.g. bile salts, organic solvents, ethoxydiglycol, or interesterified stone oil (column 2, third full paragraph). In certain embodiments, the excipient comprises between about 60 to 90% by weight lipophilic carrier, between about 5 to 25% mucoadhesive agent, and between abut 5 to 20% penetration enhancer (column 2, lines 60-67).

Examiner argues that in another embodiment, the formulation comprise between about 5-20% sorption promoter (column 8, lines 31-34).

Examiner specifically recites the instant Claim 54 as: "wherein said penetration enhancer is present in amount from about 0.1% to about 60%, by weight, wherein said mucoadhesive agent is present in from about 0.5% to about 10%, by weight, and wherein said release modifier is present in amount from about 5% to about 70%, by weight."

Applicants disagree. The above mentioned materials are not necessary for formation of foams or films according to the instant

invention. They may or may not be added to the substrate polymer for certain specific drugs, or on order to enhance or slow a release rate of the drug from the film or foam or to enhance a rate of absorption.

Examiner maintains that, thus, the claimed invention is anticipated by Harrison et al., because the limitations of the instant invention overlaps with Harrison et al., for the reasons stated above.

Applicants disagree. Applicants have shown in a very detailed analysis of each and every Examiner statement that Harrison does not anticipate the instant invention. Moreover, the previously rejected claims are canceled and the new claims 59-86 are more specifically distinguished from the Harrison reference. The rejection should be withdrawn. It is so respectfully requested.

Rejection under 35 USC § 103

Claims 47-58 are rejected as being unpatentable over Partain III et al. (US Patent 4,946,870), in view of Igarashi (US Patent 4,997,653), in further view of Durrani (US Patent 6,159,491).

Examiner argues that Partain III, et al. (US Patent 4,946,870) delivery systems are useful for the topical delivery of pharmaceutical or therapeutic actives which can be administered to a desired topical or mucous membrane site of a subject, and wherein upon delivery, the systems provides a biocompatible substantive, gas permeable, film from which actives are available at the designated site (see especially abstract, col. 2, lines 8-26; and col. 10, lines 23-29).

Partain et al. teach that the said delivery system is comprised of from about 0.01 to about 99.99 weight percent of at least one aminopolysaccharide selected from the group consisting of 1) chitosonium polymers, and 2) covalent chitosan derivatives (col. 2, lines 29-50; col. 3, line 61 to col. 4, line 61); chitosan derivatives

are known in the art to be mucoadhesive or bioadhesive agents.

Partain et al. teach that in many instances the delivery system comprises a chitosan derivative, an active component, one or more pharmaceutically acceptable diluents or vehicles (e.g. water, ethanol, glycerine, dimethylether, carbon dioxide, butane, polyethylene glycol, ethoxylated or propyloxylated glucose, sorbitol derivatives, and the like), wherein the chitosan derivative can be about 0.5 to about 30 weight percent of the system, with the remainder of the system being a diluent and optionally, other additives (col. 9, lines 22-68).

Examiner submits that claim 55 recites the term" wherein said composition further comprises a therapeutically acceptable additive or excipient, wherein said additive or excipient is a solubilizing agent, buffering agent, filler, preservatives, plasticizer, surfactant or anti-oxidant" reasonably overlaps with the teaching of Partain et al. additives (col. 9, lines 22-68).

Examiner submits that claim 54 recites the term "wherein said mucoadhesive agent is present in from about 0.5% to about 10%, by weight," which overlaps with the teaching of Partain et al. additives (col. 9, lines 22-68).

Examiner submits that claim 52 recites the term "mucoadhesive agent."

Examiner submits that Partain et al. teach that typical sites for topical delivery include application to the dermal, ophthalmic and mucous membranes and tissues such as the skin, eyes, ears, mouth, nose, throat, rectum, vagina and urethra (col. 1, lines 49-52).

Examiner submits that Partain et al. teach that the active/chitosan derivative mixture may be applied to the skin or mucosa in the form of a pre-formed film, sponge, powder, or other composites

(col. 3, lines 20-52; and col. 10, lines 23-29).

Examiner submits that instant claim 47 recites the term "wherein said foam or film device is preformed into a solid or semi-solid tampon, foam tablet, foam cylinder, foam or film strip, foam or film pad, foam or film pillow, foam or film tube, foam or film sheet, foam or film sphere, foam or film ring, foam bead or a single or double sided foam or film sheet, or is a liquid preparation that forms a foam or film layer device upon contact with an epithelial tissue or with a surface of non-foam or non-film device made of different material."

Examiner submits that claim 50 recites the terms "tampon, ... ring, strip, sheet, tube, ... " which overlaps with the teaching of Partain et al. (col. 3, lines 20-52).

Examiner submits that claim 58 recites the term "wherein said therapeutically effective agent is incorporated into said foam before the foam formation or be coated on the inner pores of prefabricated foam".

Examiner argues that Partain et al., teaches that chitosan derivatives are good humectants; the humectant properties enhance the absorption of the actives into the tissues (col. 3, lines 53-60) and also many pharmaceutical and therapeutic actives, including anti-inflammatory analgesics (e.g. salicyclic acid, diflunisal, acetaminophen, sulindac, ibuprofen, ketoprofen, naproxen), local anesthetics, antibiotics (e.g. erythromycin, clindamycin), antiviral agents (e.g. acyclovir), antifungal agents (e.g. miconazole), calcium channel blockers (e.g. diltiazem), vasodilators (e.g. nitroglycerine), and autacoids (e.g. oxytocin, vasopressin, leukotrienes, endorphins, and other pharmaceutically active peptides) wherein the concentration of the actives in the delivery system vary from as little as 0.0001 up

t 5 percent or higher, by weight of the delivery system (col. 8, line 7 to col. 9, lines 45-48).

Examiner submits that claim 48 recites the term "non-steroidal anti-inflammatory agent, vasodilatory agent, calcium channel anagonists agent, local anesthetic agent, antimicrobial agent... ;" claim 49 recites the terms "naproxen," diltiazem, nitroglycerin, miconazole, acyclovir, oxytocin," for example.

Examiner submits that Partain et al. teach that additives for the enhanced percutaneous absorption of various pharmaceutical or therapeutic actives include propylene glycol, glycerol, urea, diethyl sebecate, sodium lauryl sulfate, sodium laureth sulfate, sorbitan ethoxylates, nicotinate esters, oleic acid, pyrrolidone carboylate esters, N-methyl pyrrolidone); a wide variety of other actives can be employed either alone or in combination (col. 9, lines 22-39).

Examiner submits that claim 53 recites penetration enhancers e.g. propylene glycol and glycerol; claim 51 recites the term "polyethylene glycol."

Examiner submits that Partain et al. exemplify mineral oil (see col. 10, line 54 to col. 11, line 24).

Examiner submits that Claim 53 recites the term "mineral oil" as being an example of a release modifier. The term "wherein said release modifier is present in amount from about to about 5% to about 70%, by weight," as recited in claim 54, for the purposes of this rejection, given its broadest reasonable possible interpretation is construed to overlap with the teaching of Partain et al. (see col. 10, line 54 to col. 11, line 24).

Examiner submits that the limitations recited in claims 56, 57, and 58 are reasonably construed to be coextensive characteristics of

the claimed invention. Partain et al. do not teach Ota's ring, or collagen, or anti-neoplastic drugs.

Applicants disagree. Applicants respectfully submit that the claims 48-58 are canceled and the newly added claims 59-86 do not claim chitosan containing compositions that are the same as those of Partain. The Partain et al., reference is thus not applicable and should be withdrawn.

Examiner further argues that Igarashi (US Patent 4,997,653) teaches T-shaped or Ota's ring-like intrauterine preparations having a single-layer structure, or a two-layer structures in which a core comprising a piece of Silascon Rod or other material is embedded (col. 2, lines 24-68). Igarashi teaches that preparations comprise 20 to 50 parts by weight of the active component, or danazol, 50 to 80 parts by weight of a matrix base, and optionally 0.5 to 8 parts by weight of a release-promoting agent (col. 3, lines 21-52).

Claim 56 recites the term "a single layer or multiple layers of a single or double-sided sheet, "which is construed to be satisfied by the teaching of Igarashi (col. 2, lines 24-68).

Examiner submits that Igarashi teaches that the matrix base may be selected from various polymeric compounds including silicone rubber (polydimethylsiloxane), polymethyl methacrylate, polyhydroxy methacrylate, polyethylene glycol, polyvinyl alcohol, and collagen; polydimethylsiloxane, silicone-carbonate copolymer, ethylene-vinylacetate copolymer, ethylene-vinylacetate copolymer and ethylene-vinylalcohol copolymer are the most preferred for the retention and release of danazol (col. 3, line 53 to col. 4, line 42).

Applicants disagree. Claims 46-58 are canceled. However, neither the canceled claims or the new claim are directed to the T-shaped or

Ota ring structures and do not contain a Silascon rod (Silicon resin).

The reference should be withdrawn.

Examiner further argues that Durrani (US Patent 6,159,491, already made of record) teach bioadhesive, prolonged release drug composition comprising a synergistic formulation of carrageenan, acrylic acid containing polymers, agarose and an effective amount of a therapeutic agent (column 6, line 10-13).

Examiner submits that Durrani et al., disclose an embodiment containing acrylic containing polymer such as polycarbophil, a homopolymer such as acrylic acid and divinyl glycol, a copolymer of acrylic acid and a selected C10 to C30 alkyl acrylate copolymer (column 6, lines 19-26).

Examiner submits that Durrani teaches that one or more of the therapeutic agents dispersed or dissolved within the bioadhesive, prolonged release drug composition may be selected from drugs, including, for example, anti-inflammatory, antineoplastic or an analgesic agent. Durrani discloses a bioadhesive vaginal gel dosage form designed to incorporate a therapeutic agent for local or systemic action when administered intravaginally.

Applicants disagree. Duranni discloses a bioadhesive synergistic gel composition. Such composition is clearly not a device, foam or film. Reference is not relevant and should be withdrawn, particularly in view of the new claims.

Examiner concludes that based on the teaching of Partain et al., systemic administration of drugs is associated with certain undesirable effects, someone of skill in the art would have been motivated to combine the above cited prior art teachings to create the instant inventive concept. Thus, someone of skill in the art at the time the

instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

Applicants disagree. No single reference cited herein or a combination of two or three references makes the instant invention obvious. The rejection should be withdrawn and the new claims passed to issue. It is so respectfully requested.

SUMMARY

In summary, claims 47-58 are canceled and the new claims 59-86 are added. Arguments are submitted to overcome rejections under 35 USC 102, 103 and 112. With the submission of new claims, it is believe that all rejections are overcome and the claims are in conditions for allowance. Notice of Allowance is respectfully solicited.

Respectfully submitted,
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Dated: February 21, 2008

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